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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/875,994	06/08/2001	Bruno Biatry	208594US0	8350
22850	7590	11/30/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			YU, GINA C	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/875,994

Applicant(s)

BIATRY, BRUNO

Examiner

Gina C. Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24,26-31 and 37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24,26-31 and 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Receipt is acknowledged of amendment filed on August 27, 2004. Claims 1-24, 26-31, and 37 are pending. Claim rejection made under 35 U.S.C. § 112, second par., as indicated in the previous Office action dated April 7, 2004 is withdrawn in view of applicants' remarks. Claim rejections made under 35 U.S.C. §§ 112, first par., 102, and 103 are maintained for the reasons of record and modified to address the new claim submitted by applicants. Obvious double patenting rejection is withdrawn in view of the terminal disclaimer filed on August 27, 2004.

### ***Terminal Disclaimer***

The terminal disclaimer filed on August 27, 2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of patent application serial number 09/875,993 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-24, 26-31, and 37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for protecting skin, does not reasonably provide enablement for protecting "keratin materials". Similarly, the disclosure fails to enable for all "pollutions", although specification enables for protecting skin against carbon-14 radio labeled particles. The specification does not enable any person skilled

in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether any necessary experimentation is "undue" include, but are not limited to: the breath of the claims; the nature of the invention; the state of the prior art, the level of one of ordinary skill; the level of predictability in the art; the amount of direction provided by the inventor; the existence of working examples, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. See In re Wands, 858 F.2d 731, 737, 8 U.S.P.Q. 2d 1400, 1404 (Fed. Cir. 1988).

In this case, applicants claim the method of protecting all types of "keratinous materials". While keratin materials may include human nail and hair, or even synthetic keratin, applicants' disclosure merely shows skin treatment compositions and the method of using the compositions. See spec. p. 14-17. Furthermore, claim 24 recites "reducing the desquamation of keratin materials and/or preventing an increase in sebum flow from a keratin material". Human nails or hair would not undergo desquamation nor sebum flow. There is no guidance, working example, or reasonable predictability of the efficacy of the invention with respect to the keratin materials other than skin.

With regards to "pollutions", examiner views that the term pollution may include contamination by either chemical or waste products, and not only the specific type of pollutant applicants used to demonstrate the efficacy of the invention. There is no guidance, working example, or reasonable predictability of the efficacy of the invention with respect to the all type of pollution other than carbon-14 radio labeled particles.

Applicants' disclosure fails to enable the claimed method of protecting all keratin materials, as undue experimentation is necessary to determine the efficacy of the invention as claimed.

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-24, 26-31, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Ribier et al. (U.S. Pat. No. 6,071, 524) ("Ribier I").

Ribier I discloses compositions for skin, where in an oily phase, stabilized by cubic gel particles formed of phytanetriol, is dispersed in an aqueous phase. See col. 1, line 7- col. 2, line 18. See Examples 6 and 7, which are directed to day creams for skin protection. The reference further discloses the specific limitations of instant claims 7-22, 27, and 30. See col. 3, line 9 – col. 9, line 19.

Topically applying a cosmetic is an inherent use of the composition. The claimed method is inherently practiced by any users of the Ribier I invention.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1, 23, 24, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Derwent Acc. No. 1986-321473 (English abstract of JP 61236737 A) ("Kuraray abstract" hereunder).

Kuraray abstract states, "[p]hytanetriol is known as useful cosmetic component with protective action for skin or hair." See Basic-Abstract.

While the reference does not specifically teach what is "the effective amount to protect the skin from pollution penetration", the claim limitation does not specifically set forth the actual amount. Given the general teaching of the protective function of phytanetriol, one having ordinary skill in the art at the time the invention was made would have discovered the workable amount of the active ingredient by routine experimentation.

2. Claims 2, 3, 5, 6, 15, 17-19, 21, and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuraray abstract as applied to claims 1, 23, 24, and 37 above, and further in view of Ribier et al. (U.S. Pat. No. 5,834,018) ("Ribier II").

Kuraray abstract, discussed above, fails to teach the specific formulation of the composition.

Ribier II teaches aqueous composition of cubic gel particles based on 0.1-15% by weight of phytanetriol. See abstract.

Given the general teaching that phytanetriol provides protective action for skin, a one having ordinary skill in the art at the time the invention was made would have been motivated to look for specific formulations comprising phytanetriol such as Ribier II and applied the prior art invention with the expectation that the Ribier invention would successfully protect the skin.

3. Claims 2-4, 26, 28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuraray abstract as applied to claims 1, 23, and 24 as above, and further in view of Murad (U.S. Pat. No. 6,207,694 B1).

Kuraray abstract, discussed above, fails to teach the specific formulation of the composition.

Murad teaches a composition for prevention and treatment of hair and scalp condition comprising phytanetriol. See abstract; Examples 2, 3, 5, and 7-9. The use of the composition encompasses reducing hair and scalp damages from exposure to pollution or overdrying. See instant claims 1, 23, and 24. See col. 5, lines 5 – 12; 9, lines 17 – 21. Examples 2, 3, 5, and 7-9 illustrate formulations comprising phytanetriol in the amount of 0.02 – 0.3 % by weight of the total composition. See instant claims 2 and 3. The formulas are also homogenous mixture of oil and aqueous phases. See instant claims 4, 26, and 29 are met. Examples 5, 7, and 8 are directed to scalp formulation. See instant claims 28 and 31.

Given the general teaching that phytanetriol provides protective action for hair or skin, a skilled artisan would have been motivated to look for the specific formulations such as the Murad invention, and to apply the composition with the expectation that it would successfully protect hair and scalp.

4. Claims 2-4, 26, and 29 are rejected under 35 U.S.C. § 103 (a) as unpatentable over Kuraray abstract as applied to claims 1, 23, and 24 above, and further in view of Bergmann (U.S. Pat. No. 6,110,450).

Kuraray abstract, discussed above, fails to teach the specific formulation of the composition.

Bergmann teaches composition for the treatment and protection of hair, comprising glycoceramide and phytanetriol. See abstract. The term "protection" in the reference includes the protection of the hair fibers from the harmful agents from unsuitable hair treatments (and inclement weather). See col. 1, line 17 - 26. Examiner views that applicant's broad definition of pollutant, which include gases or "heavy metals", encompasses the harmful metal agents from the hair treatment products. See spec. p. 2, lines 22-24. Examples 1 and 2 show emulsion formulations comprising phytanetriol in the amount of 0.1 % by weight of the total composition. See instant claims 2-4, 26, and 29.

Given the general teaching that phytanetriol provides protective action for hair or skin, one having ordinary skill in the art at the time the invention was made would have been motivated to apply the Bergmann composition with the expectation that the Bergmann invention would successfully protect hair and scalp.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-24 and 26-31 have been considered but are unpersuasive.

Applicants argue that the present claims should be allowed in view of Jansen v. Rexall Sundown Inc. See 68 U.S.P.Q. 2d 1154 (CAFC 2003). Examiner is of position that the Jansen case should be distinguished from the present case. The Jansen patent was allowed after narrowing down the scope of the claims to the specific method



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of treating or preventing macrocytic-megaloblastic anemia by administering folic acid/vitamin B complex in high dose to the patients who are in need thereof. The court there found no infringement by Rexall who manufactured and sold the same composition over the counter with a label stating that the product can be used for maintenance of blood homocysteine levels. The court reasoned that there is no evidence that Rexall's consumers knowingly used the product with intent to treat or prevent macrocytic-megaloblastic anemia.

In Jansen, the court was able to classify the users of the same folic acid/ vitamin B complex into two groups: those who take the product with intent to treat or prevent macrocytic-megaloblastic anemia, and those who take it with intent to maintain blood homocysteine levels. In this case, however, there such clear distinction cannot be made. Both users of the Ribier and the present invention use the phytantriol cubic gel composition with the same intent and purpose, which is **to protect the keratin material or skin** (ultimately from skin dehydration and aging). See applicants' spec. p. 2, first full par.; Ribier, Examples 7-9.

Even in applicants' own disclosure applicants stated that skin is dehydrated and forms wrinkles and lines as a result of the exposure to pollutants. The prior art teaches that the applicants' composition, the phytantriol-containing cubic gel, is used in variety of cosmetic compositions, including day cream, anti-aging day cream, hydrating milk, and day fluid, which all used to protect the skin from aging, exposure to harmful environment, and dehydration. Examiner views that the users of the Ribier composition also applies the same composition to achieve the same result, i.e., to dehydrate skin

and protect the skin from early signs of aging, wrinkles, and lines. See Example 12, which teaches that the composition "protects the skin against the harmful effects of free radicals". Examiner is of opinion that, the method of protecting skin by using an old and well-known composition could not be granted a patent every time an applicant claims to have discovered a new means of how the skin is damaged or established the mechanism of how the known composition protects the skin. Regardless of whether the users of the Ribier composition know that by applying the Ribier composition their skin would be protected from pollutants or free radicals, in examiner's view those users have the same purpose and intent to use the composition as the population described by the present applicants.

Applicants assert that the Rapoport court supports their position. See Rapoport v. Dement, 254 F.3d 1053 (Fed. Cir. 2001). Applicants argued that the court there rejected inherency argument firstly because the prior art did not disclose administering the buspirone to patients suffering from sleep apnea. Secondly, applicants also noted that "it had not been demonstrated that the prior art regiment would necessary result in treating sleep apnea even assuming such a regiment were administered to on suffering from sleep apnea". Examiner respectfully notes that the rationale for such findings on the inherency issue was that the prior art only disclosed administering the composition to volunteers who do not suffer from sleep apnea without specifying to take the dosage at bedtime, which is when sleep apnea occurs. Thus it was evident that the users of the prior art did not necessarily result in practicing the claimed method. However, in this case, the exposure to pollution is not a symptom like sleep apnea which only a specified

group of population experiences nor does it require medical prescription (which is evidence of intent, see Jansen at 1159). Examiner takes the position that population in general is exposed to pollution in one way or another, even during operating or riding in an automobile, for example. Unlike in Rapoport, there is no distinction between the population who are “in need” of the applicants’ invention, and the practice of the prior art method inherently anticipates the claimed invention.

With respect to the § 103 rejection, applicants assert that Kuraray “merely discloses that phytanetriol protects hair and skin, but does not state how or from what such protection occurs”. Examiner views that the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See Ex parte Obiaya, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). The Kuraray reference teaches the motivation for a skilled artisan to use the composition with the intent to protect the skin or hair. Examiner views that applicants’ discovery of how or why phytanetriol works cannot be the basis for patentability, as the protection of skin or hair from pollution naturally flows from topically applying the Kuraray composition as taught.

With respect to the enablement rejection, applicants stated “the specification is enabling where the keratin material is skin”. This is incorrect, as the rejection also indicated that the claim is not enabling with respect to “pollution”, since only radio-labeled carbons are used in the specification. Applicants assert that applicants cannot be expected to exemplify each and every combination to satisfy the enablement

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requirement, for it would be unduly burdensome and time consuming. While examiner agrees, in the instant application, the undue burden falls on the one of ordinary skill in the art to make and use the present invention as claimed because there is no disclosure as to how to protect the keratinous materials from "pollution" other than carbon monoxide. Examiner does not believe that a skilled artisan would reasonably find the applicants' disclosure would reasonably enable a skilled artisan to make and use the claimed invention to protect the keratinous materials from other chemicals.

### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

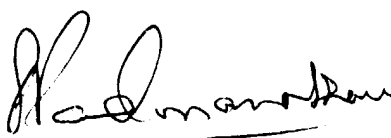
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-0635.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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